UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,739	02/14/2001	Surya K. Goli	PF-0162-3 DIV	3353

7590 08/26/2003

LEGAL DEPARTMENT
INCYTE GENOMICS INC.
3160 PORTER DRICR
PALO ALTO, CA 94304

EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/784,739	GOLI ET AL.
	Examiner	Art Unit
	Ja-Na Hines	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4 and 8* is/are pending in the application.

4a) Of the above claim(s) *1,5-7 and 10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____

Amendment Entry

1. The amendment filed March 18, 2003 have been entered. The examiner acknowledges the amendment to the specification. Claims 2 and 8 have been amended. Claim 9 has been cancelled. Therefore claims 2-4 and 8 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) the objection of claims 2-4;

b) the enablement rejection of claims 2-4 and 8-9 under 35 U.S.C. 112, first paragraph;

c) the rejection of claims 2-4 under 35 U.S.C. 112, second paragraph,

d) the rejection of claims 8-9 under 35 U.S.C. 102(b) as being anticipated by Hillier et al., (Accession Number H27975); and

e) The rejection of claims 2-4 under 35 U.S.C. 103(a) as being unpatentable over Hillier et al., (Accession Number H27975) in view of Simula et al.

Election/Restrictions

3. Applicants assert that upon allowance of the product claims, rejoinder of the

However, as stated in the previous office actions, the methods of Groups V, VI, X and XI are distinct as claimed because they have different methods with different method steps; different functions; and the effects have different final outcomes when compared to the other groups. Therefore, the inventions are unrelated and the requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

4. Applicant's arguments filed March 18, 2003 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The written description rejection of claims 2-4 and 8-9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are now drawn to an isolated polynucleotide encoding a polypeptide

having at least 90% sequence identity to the sequence of SEQ ID NO:1 over the entire length of SEQ ID NO:1 and an isolated polynucleotide comprising a sequence selected from the group consisting of a) a polynucleotide sequence of SEQ ID NO:2; b) a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2; c) a polynucleotide sequence complementary to a); d) a polynucleotide sequence complementary to b); and e) a ribonucleotide equivalent of a)-d).

The written description is not commensurate in scope with the claims drawn to a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 over the entire length of SEQ ID NO:1 and a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2.

Applicants urge that given SEQ ID NO:1 or 2, one of ordinary skill in the art would recognize a polynucleotide encoding naturally-occurring variants of SEQ ID NO:1 or 2 having at least 90% sequence identity to SEQ ID NO:1 or 2. However, contrary to applicants assertion there is no disclosure of naturally occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 and 2 over the entire length of sequences. The structural and chemical features described on page 12 fail to describe naturally occurring sequence variations having at least 90% sequence identity to SEQ ID NO:1 and 2 over their entire length. The use of BLAST fails to adequately describe the naturally occurring sequence variations, rather BLAST simply compares sequence identity, it does not provide a means for the disclosure of naturally occurring sequences having at least 90% sequence identity to SEQ ID NO:1 and 2 over their

Applicants urge that the written description rejection is based upon a means for unduly limiting the scope of the claims; however, the rejection is maintained because the specification fails to adequately described naturally-occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 over the entire length of SEQ ID NO:1 and naturally-occurring polynucleotide sequences having at least 90% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2.

Applicants assert that the instant claims specifically define the claimed genus through the recitation of chemical structure because the instant claims are fundamentally different from the claimed subject matter found invalid in *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) and *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) thus, the instant claims satisfy the written description requirement of *Lilly* and *Fiers*.

However it is the examiner's position that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). There is no disclosure of naturally occurring amino acid sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 over the entire length of SEQ ID NO:1 and naturally occurring polynucleotides sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2.

The instant case, like *Fiers* fails to have a description of a naturally occurring

sequence will naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Contrary to applicants statements, the instant claims fail to define the polynucleotides in terms of chemical structure, as applicants have not described what the naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2 are. Neither have applicants described the process by which they can determine what the naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 nor 2 over the entire length of SEQ ID NO:1 or 2 will be.

Applicants argue that the instant claims do not describe a genus that could be characterized as highly diverse and that the variation is low. However the instant claims are drawn to naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2, yet there is no written description drawn to the variation of the naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Applicants have failed to describe how to predict what the naturally occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Furthermore any variant or mutant that has similar sequence identity yet has a different function is also encompassed by the claims. Applicants have not taught examples of such polynucleotides and ribonucleotides. Thus, the structure of sequences or complementary polynucleotides that encode a polynucleotide having sufficient glutathione S-transferase activity have not defined and broaden the scope of the

Applicants assert that the state of the art at the time of the present invention is further advanced than at the time of the *Lilly* and *Fiers* applicants and therefore applicants' work has been adequately described. However, despite applicants assertion, there is no assay for determining naturally occurring sequences which support allowing one of skill in the art to screen for such naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. These naturally occurring variant sequences are not described. The specification does not provide written description support for any naturally occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. The specification fails to describe how to predict such natural occurrences.

It is noted that applicants response centers on the *Lilly* and *Fiers* cases, however the written description requirements are broader than the holdings of those two cases. Even though the claims recite a sequence identification number, the skilled artisan cannot envision the detailed structure of the encompassed naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. It is noted that the naturally occurring variations can vary at critical residues, yet the claims fail to define or take into account what the 10% naturally occurring variables will be. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). There is no written description support that the inventors control what naturally occurs. There is no written description support that the inventors invented naturally occurring variants having at least 90% sequence identity to the

occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2 or complementary sequences comprised within the family of enzymes. Thus, the structure of these naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2 or polynucleotides is not defined. Moreover, a skilled artisan cannot envision the detailed structure of complementary sequences. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity or the advances in technology. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The nucleic acid itself is required.

Thus the claims fail to recite the precise definition of the naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Therefore, the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph and the rejection is maintained.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. The rejection of claim 8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-4 of U.S. Patent No.5,817,497 is maintained.

Applicants request that the requirement for submission of a terminal disclaimer be held in abeyance is noted, however the rejection will be maintained until the terminal disclaimer is received.

Declaration

8. Applicants submitted a declaration of Todd Bedilion, Ph.D. This declaration urges that that the specification enables that use of the polynucleotide sequences. Moreover, the declaration is directed determining that the specification and claims are enabled and that that a person skilled in the art would have been enabled to make and use the polynucleotides. The declaration under 37 CFR 1.132 filed March 31, 2003 is sufficient to overcome the enablement rejection of claims 2-4 and 8 because the Declaration states with additional scientific evidence how to make and use the claimed polynucleotides.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
July 23, 2003

NITA MINNIFIELD
PRIMARY EXAMINER
7/28/03